

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 25, 2007

MEMORANDUM

SUBJECT: Review of "*Determination of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residue on the Hand from Treated Vinyl Flooring Sections Following Hand Press on Untreated Surfaces*"

FROM: Dana Vogel, Senior Scientist
Chemistry and Exposure Branch (CEB)
Health Effects Division (7509C)

A handwritten signature in black ink, appearing to be "D. Vogel", written over the name Dana Vogel.

THRU: Jeff Evans, Branch Senior Scientist
CEB
Health Effects Division (7509C)

A handwritten signature in black ink, appearing to be "J. Evans", written over the name Jeff Evans.

TO: Cathryn O'Connell
Special Review and Reregistration Division (7508C)

DP Barcode: 336758
PC Code: 069001
MRID Number: 46188614

Attached is a review of the MRID 46188614 "*Determination of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residue on the Hand from Treated Vinyl Flooring Sections Following Hand Press on Untreated Surfaces*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the amount of residue left on a hand exposed to vinyl flooring treated with a formulation containing pyrethrin (PY) and piperonyl butoxide (PBO) following hand contact with untreated vinyl flooring surfaces. The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED).

Results

In this study, three test rooms (Simulated Residential Rooms (SRRs)) were used, with one containing the application equipment (the sprayboom). Sixty-six vinyl flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. Application of the test material to the flooring was made using a sprayboom apparatus. The desired deposition rate of the test material onto the vinyl flooring was $3.96 \mu\text{g}/\text{cm}^2$ for PY and $7.87 \mu\text{g}/\text{cm}^2$ for PBO. Total deposition was measured using deposition coupons, which were collected after application of the test material, followed by a drying period. After collection of the deposition coupons, four vinyl flooring sections were removed and moved to a hand press room. Two male test subjects performed one hand press on the treated surface and 4 separate hand presses on untreated pieces of vinyl flooring. Each subject performed hand presses with each hand, for a total of four replicates. The subjects' hands were then cleaned with isopropyl alcohol dressing sponges to remove any remaining residues. The dressing sponges were extracted and then analyzed using GC/MS.

The study author calculated hand residues based on the dressing sponges and hand surface area measurements for PY and PBO. Hand residues averaged $28.5 \text{ ng}/\text{cm}^2$ for PY and $38.4 \text{ ng}/\text{cm}^2$ for PBO. The study author reported the average deposition coupon residues as $4.15 \pm 1.18 \mu\text{g}/\text{cm}^2$ for PY and as $9.12 \pm 2.22 \mu\text{g}/\text{cm}^2$ for PBO. The percent residue of PY and PBO on the hands was reported to be 0.69% and 0.42% of the PY and PBO applied to the vinyl flooring, as determined from the deposition coupons.

Versar also calculated hand residues based on the data provided for dressing sponges and hand surface area measurements. Hand residues for PY were corrected for a field fortification recovery of 83% and deposition coupons were corrected for field fortification recoveries of 70.3% for PY and 62.8% for PBO. Hand residues averaged $34.3 \text{ ng}/\text{cm}^2$ for PY and $38.4 \text{ ng}/\text{cm}^2$ for PBO. Corrected deposition coupon residues averaged $5.91 \pm 1.68 \mu\text{g}/\text{cm}^2$ for PY and $14.52 \pm 3.54 \mu\text{g}/\text{cm}^2$ for PBO. PY and PBO residues on the hand were estimated by Versar to be 0.58% and 0.26% of the PY and PBO applied to the vinyl flooring, as determined from the deposition coupons.

It should be noted that the Study Report does not provide information on the determination of the LOQ for PY. The Study Report states that the residue data for PY were determined using the PYI data and a conversion factor of 1.842, however, Versar was unable to verify the LOQ provided for PY using this conversion factor and the LOQ provided for PYI.

Conclusions

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, both the performance of this study and the data generated in this study conformed to the criteria set forth in the protocol and guidelines. HED believes the data within this study is of high quality and valid for risk assessment purposes.

Reviewers: Kelly McAloon/Linda Phillips

Date: February 26, 2004

STUDY TYPE: Active Transfer; Vinyl

TEST MATERIAL: Pyrethrin and Piperonyl Butoxide; pre-fill batch formulation (similar to that for an indoor fogger formulation)

SYNONYMS: Pyrethrin (PY) and Piperonyl Butoxide (PBO)

CITATION:

Author(s):	Sami Selim, Ph.D.
Study Director(s):	Robert E. Rogers, Ph.D, D.A.B.T., P.Biol.
Title:	<i>Determination of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residue on the Hand from Treated Vinyl Flooring Sections Following Hand Press on Untreated Surfaces</i>
Study Completion Date:	August 25, 2002
Testing Facility:	Toxcon Health Sciences Research Centre Inc. 9607 - 41 st Avenue Edmonton, Alberta Canada T6E 5XL
Analytical Facility:	Enviro-Test Laboratories/XENOS Division Unit 13 - 210 Colonnade Road Nepean, Ontario Canada K2E 7L5
Identifying Codes:	Toxcon Project Id: 00-039-PY01 Xenos Project No.: XEN00-38

SPONSOR: Non-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews “*Determination of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residue on the Hand from Treated Vinyl Flooring Sections Following Hand Press on Untreated Surfaces*” submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the amount of residue left on a hand exposed to vinyl flooring treated with a formulation containing pyrethrin (PY) and piperonyl butoxide (PBO) following hand contact with untreated vinyl flooring surfaces.

Three test rooms (Simulated Residential Rooms (SRRs)) were used, with one containing the application equipment (the sprayboom). Sixty-six vinyl flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. Application of the test material to the flooring was made using a sprayboom apparatus. The desired deposition rate of the test material onto the vinyl flooring was $3.96 \mu\text{g}/\text{cm}^2$ for PY and $7.87 \mu\text{g}/\text{cm}^2$ for PBO. Total deposition was measured using deposition coupons, which were collected after application of the test material, followed by a drying period. After collection of the deposition coupons, four vinyl flooring sections were removed and moved to a hand press room. Two male test subjects performed one hand press on the treated surface and 4 separate hand presses on untreated pieces of vinyl flooring. Each subject performed hand presses with each hand, for a total of four replicates. The subjects' hands were then cleaned with isopropyl alcohol dressing sponges to remove any remaining residues. The dressing sponges were extracted and then analyzed using GC/MS.

The study author calculated hand residues based on the dressing sponges and hand surface area measurements for PY and PBO. Hand residues averaged $28.5 \text{ ng}/\text{cm}^2$ for PY and $38.4 \text{ ng}/\text{cm}^2$ for PBO. The study author reported the average deposition coupon residues as $4.15 \pm 1.18 \mu\text{g}/\text{cm}^2$ for PY and as $9.12 \pm 2.22 \mu\text{g}/\text{cm}^2$ for PBO. The percent

residue of PY and PBO on the hands was reported to be 0.69% and 0.42% of the PY and PBO applied to the vinyl flooring, as determined from the deposition coupons.

Versar also calculated hand residues based on the data provided for dressing sponges and hand surface area measurements. Hand residues for PY were corrected for a field fortification recovery of 83% and deposition coupons were corrected for field fortification recoveries of 70.3% for PY and 62.8% for PBO. Hand residues averaged 34.3 ng/cm² for PY and 38.4 ng/cm² for PBO. Corrected deposition coupon residues averaged 5.91 ± 1.68 µg/cm² for PY and 14.52 ± 3.54 µg/cm² for PBO. PY and PBO residues on the hand were estimated by Versar to be 0.58% and 0.26% of the PY and PBO applied to the vinyl flooring, as determined from the deposition coupons.

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.

- The test product was not identified and no label was provided.
- Calibration procedures for the application equipment were not provided in the Study Report.
- The Study Report does not provide information on the determination of the LOQ for PY. The Study Report states that the residue data for PY were determined using the PYI data and a conversion factor of 1.842, however, Versar was unable to verify the LOQ provided for PY using this conversion factor and the LOQ provided for PYI.
- The blank deposition coupon sample results were not provided in the Study Report.
- There was only one replicate per field fortification level.
- The study author did not correct the PY residue data for the field fortification recovery, which was below 90%.

COMPLIANCE:

Signed and dated GLP and Data Confidentiality statements were provided. A Quality Assurance statement was not provided in the Study Report. The Study Report noted that the study was not performed according to the U.S. EPA FIFRA Good Laboratory Practice Regulations currently in effect (40 CFR, Part 160), however, all data collection and study conduct was performed “in the spirit of GLP.” The data generated at Toxcon was not audited and the data and Analytical Report generated at Xenos were reviewed by Xenos’ Quality Assurance representative.

GUIDELINE OR PROTOCOL FOLLOWED:

The study was conducted following Xenos and Toxcon Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 00-039-PY01).

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation:	An unidentified pre-fill batch fogger formulation similar to that for an indoor fogger; developed by McLaughlin Gormley King Company (MGK); contains 0.77% PY (wt/wt) and 1.64% PBO (wt/wt) as the active ingredients.
Lot/Batch # formulation:	LPB47000a
Formulation guarantee:	Certificate of analysis provided
CAS #(s):	Pyrethrin (PY): 8003-34-7 PBO: 51-03-6
Other Relevant Information:	Toxcon ID No.: PY01T006

2. Relevance of Test Material to Proposed Formulation(s):

Pyrethrin and piperonyl butoxide are active ingredients used in formulated consumer products intended for use in residential buildings. The product used was a pre-fill batch formulation similar to that of an indoor fogger formulation developed by McLaughlin Gormley King Company (MGK). The name and label for the test product was not provided with the study.

B. Study Design:

There was one amendment to the study protocol. The amendment was that the moisture content at five different areas on the palmar surface of the right and left hands of both subjects was taken after hand washing and prior to hand pressing in order to provide additional data for possible future use.

1. Site Description:

Test locations:	The test site was located at the Toxcon Health Sciences Research Centre in Canada. Three test rooms (Simulated Residential Rooms (SRRs)) were used with one containing the application equipment (the sprayboom). The rooms were prepared according to Toxcon SOP No. E-025: <i>Preparation of Test Rooms Prior to an Experiment</i> and SOP No. M-026: <i>Masking of the Test Room and the Sprayboom Prior to an Experiment</i> .
Meteorological Data:	Target test room conditions prior to application included an air exchange rate of 0.6 ± 0.1 air change per hour (ACH), a temperature of $72 \pm 4^{\circ}\text{F}$, and a relative humidity of $50 \pm 10\%$.
Ventilation/Air-Filtration:	The ventilation system for the application room was turned off (dampers closed) during application and for three hours after application. The dampers were opened after the three hours and the room conditions were adjusted to reach the conditions prior to application for a 30 minute drying period.

2. Surface(s) Monitored:

Room(s) Monitored:	Three Simulated Residential Rooms (SRRs) were used. One room contained the sprayboom apparatus and treated vinyl flooring. The other two rooms were used to perform the hand press procedure.
Room Size(s):	16 ft x 16 ft x 8 ft
Types of Surface(s):	Vinyl flooring
Surface Characteristics:	Sixty-six vinyl flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. The vinyl flooring specifications were provided in the protocol. A total of four vinyl flooring sections were removed after application (and drying), and used for the hand press procedures.

Areas sprayed and sampled: The vinyl flooring sections in one of the three SRRs used in this study were sprayed and sampled for PY and PBO residues.

Other products used: N/A

3. Physical State of Formulation as Applied : Fogger

4. Application Rates and Regimes:

Application Equipment: Sprayboom

Application Regime: One sprayboom run conducted in one SRR.

Application rate(s): An application rate was not provided in the Study Report. Application was based on the desired deposition rate of the test material onto the vinyl flooring. For PY, the desired deposition rate was $3.96 \mu\text{g}/\text{cm}^2$ and for PBO, the desired deposition rate was $7.87 \mu\text{g}/\text{cm}^2$. Target deposition rates were based on results of indoor PY and PBO total release fogger deposition studies. The sprayboom nozzle sweep speed required to obtain the desired deposition was calculated using the following equation: $U = [(Q_t)(F_a)(k_1)/(R)(n)(d)(10^{-6})]$, where U is the sprayboom nozzle sweep speed (cm/s), Q_t is the nozzle output rate (g/s), F_a is the fraction of PY in the formulation, R is the target deposition rate of PY ($\mu\text{g}/\text{cm}^2$), d is a fixed value representing the distance between nozzles (71.2 cm), n is the number of nozzles (5), and k_1 is a correction factor to account for formulation that is sprayed, but not deposited, on the test surface. The target speed was not provided in the Study Report but was reported to be documented in the raw data.

Equipment Calibration Procedures: The Study Report states that a calibrated sprayboom was used in the study, but calibration procedures were not provided. It is not certain if the equipment used in this study was consistent with the proposed use for this product. A label was not provided with the study. Therefore, the label recommended application method is not known.

Was total deposition measured? Total deposition was measured using deposition coupons. The deposition coupons consisted of squares of alpha cellulose (3 in x 3in). The coupons were backed with hexane-wiped heavy duty aluminum foil. The Study Report states that coupons were prepared according to Toxcon SOP No. M-015: *Preparation of Alpha Cellulose Deposition Coupon*. The coupons were present on the wooden platforms during test substance application.

D. Sampling:

Surface Areas Sampled: Vinyl flooring sections present on wooden platforms in SRR.

Replicates per sampling interval: Two male subjects participated in the study. Hand presses were performed with both the left and right hand of the test subjects. Each subject performed one hand press on the treated vinyl and four hand presses on the untreated vinyl flooring sections (for a total of 4 replicates; i.e., two subjects times two hands).

Number of sampling intervals: There was one sampling interval that occurred about 3.5 hours after application (i.e., 3 hours deposition period and 30 minute drying period).

Method and Equipment:	Residue deposition and transfer were determined using hand presses and deposition coupons.
Sampling Procedure(s) :	
Deposition coupons -	The deposition coupons were collected following a 30 minute drying period after application and deposition of the test material. Disposable latex gloves were worn when the coupons were handled. The coupons were folded, so that the exposed side was on the inside, and then wrapped in hexane-wiped aluminum foil.
Hand residues-	After application and collection of the deposition coupons, the vinyl flooring sections were removed and moved to a hand press room. Each section of vinyl flooring was placed in a hand press balance configuration. The transfer of residues was determined based on the applied force (~8 kg) and contact duration (~20 s). The subjects washed and dried their hands prior to the hand presses. They performed one hand press on the treated surface and then performed 4 separate hand presses on untreated pieces of vinyl flooring. After the hand presses, the subjects' hands were cleaned with isopropyl alcohol dressing sponges to remove any remaining residues. Hand palmer surface areas were determined using an ink image of the palm side of each hand, which was then scanned into a computer to create a digital image of the hand. The computerized methods of calculating surface areas are described in Toxcon SOP No. M-010.

3. Sample Handling and Storage:

Dressing sponges collected from the hand wipes were placed in separate pre-labeled 180 mL glass jars with Teflon-lined lids. Deposition coupons were placed in aluminum containers and moved to freezer storage (<-10°C) within 3 hours of collection. All samples were stored in the dark at <-10°C until shipped for analysis. Samples were shipped to the analytical laboratory overnight in an insulated cooler with dry ice.

IV. ANALYTICAL METHODOLOGIES

A. Extraction method:

Dressing sponges: Extraction was performed by sonication and mechanical shaking of the dressing sponges at room temperature with ethyl acetate. One extraction was performed and the ethyl acetate was taken to dryness by rotary evaporation. Two clean-up steps were required for the sponges, including the use of a Discovery™ polyamide SPE cartridge and an Isolute silica SPE cartridge. All sample extracts were taken to dryness and made up to an appropriate volume in toluene.

B. Detection methods: Analysis was performed using GC/MS in the EI/SIM mode. The method measured three PY esters (PYI): Pyrethrin I (P-I), Cinerin I (C-I) and Jasmolin I (J-I), and PBO. See Table 1 for specific conditions.

Table 1. Gas Chromatographic Conditions

GC Column	BD-5, ~15 m x 0.25 mm ID, 0.25 μ m film
Temperatures	Inlet: Initial - 120°C (hold 0.15 min) Prog 1 - 120-250°C @ 200°C/min (hold 10 min) Column: Initial - 90°C (hold 1.5 min) Prog 1 - 90-160°C @ 30°C/min Prog 2 - 160-175°C @ 2.0°C/min Prog 3 - 175-210°C @ 2.5°C/min Prog 4 - 210-320°C @ 50°C/min (hold 15 min) Transfer line: 280°C Mass Spectrometer trap set temperature: 225°C
Carrier Gas Flow Rate	~1.3 mL/min (constant)
Mass Spectrometer Interface	direct capillary interface
GC/MS Mode	EI/SIM
Injector Split	0 min, split ON, split ratio: 10 0.25 min, split OFF 2.00 min, split ON, split ratio: 100
Injection Volume	5.0 μ L direct injection
Rate	0.4 μ L/sec
Quantitating Mass Ions	PYI (all esters): m/z 123 ion PBO: m/z 193 ion
Approximate Retention Times	C-I ~ 17 min J-I ~ 19 min P-I ~ 20 min PBO ~ 23 min

D. Method Validation:

The analytical methods were validated in a previous study. The Study Report states that validation data for the limit of quantitation (LOQ) was taken from Xenos report XEN00-14. LOQs are reported for PYI, PY and PBO (see Table 2).

Table 2. Validated LOQs

Formulation	PYI	PY	PBO
200 μ g	0.882 μ g	1.58 μ g	3.20 μ g

Instrument performance and calibration:

Calibration solutions were prepared from the formulation by dilution in toluene. A total of 5 concentrations were used to calibrate the system: 0.010, 0.020, 0.040, 0.075, and 0.100 μ g/ μ L. The GC/MS response was determined using the prepared calibration standards to perform a linear regression analysis.

E. Quality Control:

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control dressing sponge samples were fortified with the formulated product. One of the samples was fortified at the LOQ and the other was fortified at 10x the LOQ. Results from the laboratory fortified samples are summarized in Table 3. The recovery of the low level spike for PYI was 103% versus 81.5% at the high level. The recovery of the low level spike for PBO was 110% versus 96.8% at the high level. Overall average recoveries were $92.3 \pm 15.2\%$ for PYI and $103 \pm 9.33\%$ for PBO.

Table 3. Summary of Concurrent Laboratory Fortification Recoveries

Matrix	Fortification Level (μg)		Measured Residue ($\mu\text{g}/\text{sample}$)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing sponge	0.836	3.28	0.859	3.62	103	110	92.3	103	15.2	9.33	16.5	9.03
	8.36	32.8	6.82	31.8	81.5	96.8						

Field Fortification: Samples of the dressing sponges were fortified with an amount of stock solution equivalent to $10 \mu\text{g}$ ($3\times$ LOQ) of PBO. Duplicate samples were prepared and exposed for the same time and under the same conditions as the test samples. These samples were stored and analyzed with the test samples. Field fortification results are summarized in Table 4. Overall average recoveries were $83.0 \pm 0.212\%$ for PYI and $101 \pm 2.12\%$ for PBO. The Study Report states that field fortification samples of the alpha cellulose coupons were also prepared, but the results are provided in another study (Toxcon Study 00-035-PY01).

Table 4. Summary of Field Fortification Recoveries.

Matrix	Fortification Level (μg)		Measured Residue ($\mu\text{g}/\text{sample}$)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing sponge	2.56	10	2.12	10.2	82.8	102	83	101	0.212	2.12	0.256	2.11
	2.56	10	2.12	9.94	83.1	99						

Control Samples: One blank dressing sponge and alpha cellulose coupon sample were prepared. The results for the dressing sponge are provided, however, the Study Report states that residues of the coupons were reported in a different report (Toxcon Study 00-035-PY01). All concurrent laboratory control samples for the dressing sponges had detectable residue levels that were below the limit of quantification.

Storage Stability: The field fortified samples were analyzed after a period of 7 days. The Study Report stated that this confirmed the stability of the residues over this time period.

V. RESULTS

Versar corrected residue data for field fortification recoveries below 90%. The study author did not correct for field fortification recoveries. Residues were reported for both PYI and PBO, as well as PY, which is total PY calculated from the PYI data by using a conversion factor (1.842) derived from the percentages of total PYs and PYI in the formulated product.

A. Alpha Cellulose and Deposition of Formulation:

The Study Report states that the results of the analysis of the deposition coupons were reported in a different report (Toxcon Study 00-035-PY01). The overall mean for PY is reported as $4.15 \pm 1.18 \mu\text{g}/\text{cm}^2$ and for PBO as $9.12 \pm 2.22 \mu\text{g}/\text{cm}^2$. The achieved deposition rate is reported to be 105% of the target deposition rate for PY and 116% of the target deposition rate for PBO. Versar examined the coupon residue data reported in Toxcon Study 00-035-PY01 and found that the field fortification recoveries for the deposition coupons were below 90%. Recoveries averaged 70.3% for PY and 62.8% for PBO. Therefore, Versar corrected the deposition coupon residue data. Corrected residues were calculated by Versar to be $5.91 \pm 1.68 \mu\text{g}/\text{cm}^2$ for PY and $14.52 \pm 3.54 \mu\text{g}/\text{cm}^2$ for PBO. The achieved deposition rate using these values is 149% for PY and 184% for PBO. The corrected deposition values were used by Versar in calculating the percent of PY and PBO residues transferred from the vinyl flooring to the hands.

B. Hand Residues:

Total hand residues were calculated by the study author for each hand of the test subjects. Residues are reported for PY and PBO. According to the study author, hand residues averaged $28.5 \pm 4.9 \text{ ng}/\text{cm}^2$ for PY and $38.4 \pm 4.8 \text{ ng}/\text{cm}^2$ for PBO. Versar corrected PYI residues for a field fortification recovery of 83%. Mean corrected residues for PYI, PY and PBO were 18.6 ± 3.2 , 34.3 ± 5.9 , and $38.4 \pm 4.8 \text{ ng}/\text{cm}^2$, respectively.

The percent of residue remaining on the hands after contact with one treated and 4 non-treated flooring surfaces were calculated as the ratio of the amount of residue present on the hand divided by the average residue found on the alpha cellulose coupons. The uncorrected residue found on the coupons was reported to be $4.15 \mu\text{g}/\text{cm}^2$ for PY and $9.12 \mu\text{g}/\text{cm}^2$ for PBO. When corrected for the field fortification recoveries, the coupon residues averaged $5.91 \pm 1.68 \mu\text{g}/\text{cm}^2$ for PY and $14.52 \pm 3.54 \mu\text{g}/\text{cm}^2$ for PBO. The percent of application reported by the study author using the uncorrected coupon residues was 0.69% for PY and 0.42% for PBO. The percent of application for PY and PBO calculated by Versar using the corrected coupon residues was 0.58% and 0.26%, respectively.

VI. CONCLUSION

Residues remaining on hands following contact with a treated vinyl flooring surface and 4 non-treated vinyl flooring surfaces were determined for two test subjects. The study author calculated residues based on dressing sponges and hand surface area measurements for PY and PBO. Residues averaged $28.5 \text{ ng}/\text{cm}^2$ for PY and $38.4 \text{ ng}/\text{cm}^2$ for PBO. The percent of PY and PBO deposited that was transferred to the hand after one contact with a treated surface and four contacts with untreated surfaces was reported to be 0.69% and 0.42%, respectively.

Versar also calculated hand residues based on the data provided for dressing sponges and hand surface area measurements. Hand residues for PY were corrected for field fortification recovery of 83%. Hand residues averaged $34.3 \text{ ng}/\text{cm}^2$ for PY and $38.4 \text{ ng}/\text{cm}^2$ for PBO. Deposition coupon residues were corrected for field fortification recoveries of 70.3% for PY and 62.8% for PBO. Residues averaged $5.91 \pm 1.68 \mu\text{g}/\text{cm}^2$ for PY and $14.52 \pm 3.54 \mu\text{g}/\text{cm}^2$ for PBO. The percent of PY and PBO deposited that was transferred to the hand after one contact with a treated surface and four contacts with untreated surfaces was calculated by Versar to be 0.58% and 0.26%, respectively.

LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.
- The test product was not identified and no label was provided.
- Calibration procedures for the application equipment were not provided in the Study Report.
- The Study Report does not provide information on the determination of the LOQ for PY. The Study Report states that the residue data for PY were determined using the PYI data and a conversion factor of 1.842, however, Versar was unable to verify the LOQ provided for PY using this conversion factor and the LOQ provided for PYI.
- The blank deposition coupon sample results were not provided in the Study Report.
- There was only one replicate per field fortification level.
- The study author did not correct the PY residue data for the field fortification recovery, which was below 90%.

Table 5. Summary of PY and PBO Dry Hand Press Results on Vinyl Flooring

Replicate	Measured Residue ($\mu\text{g}/\text{sample}$)			Field fortification Recovery		Corrected Residue ($\mu\text{g}/\text{sample}$)			Hand Surface Area (cm^2) ^c	Corrected Residue (ng/cm^2) ^d			% of Application ^e	
	PYI	PY ^a	PBO	PYI	PBO	PYI	PY ^a	PBO ^b		PYI	PY	PBO	PY	PBO
1(SSL)	1.49	2.74	3.54	83.0	100.5	1.80	3.30	3.54	106.1	16.9	31.2	33.4	0.53	0.23
2 (SSR)	1.97	3.63	4.69	83.0	100.5	2.37	4.37	4.69	108.4	21.9	40.3	43.3	0.68	0.30
3 (BRL)	1.44	2.65	3.50	83.0	100.5	1.73	3.20	3.50	84.0	20.7	38.0	41.7	0.64	0.29
4 (BRR)	1.21	2.23	3.43	83.0	100.5	1.46	2.69	3.43	96.8	15.1	27.7	35.4	0.47	0.24
Mean										18.6	34.3	38.4	0.58	0.26
Standard Deviation										3.2	5.9	4.8	0.10	0.03

- a PY is total PY calculated by using a conversion factor (1.842) derived from the percentages of total PYs and PYI in the formulated product.
- b No correction needed since recovery is above 90%.
- c Based on the hand palmer surface area measurements.
- d Corrected residue based on hand surface area and converted from $\mu\text{g}/\text{cm}^2$ to ng/cm^2
- e Calculated as the ratio of the amount of residue present on the hand divided by the average residue found on the alpha cellulose coupons ($4.15 \mu\text{g}/\text{cm}^2$ for PY and $9.12 \mu\text{g}/\text{cm}^2$ for PBO corrected to $5.91 \mu\text{g}/\text{cm}^2$ for PY and $14.52 \mu\text{g}/\text{cm}^2$ for PBO based on field fortification recovery data)